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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,427	10/14/2003	Stefan J.M. Kraemer	2234-2-3	7281

7590 03/06/2007
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EXAMINER

KOTINI, PAVITRA

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/686,427

Applicant(s)

KRAEMER ET AL.

Examiner

Pavitra Kotini

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/15/04, 7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, drawn to a gastric reduction device, classified in class 606, subclass 191.
- II. Claims 27-34, drawn to a method, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and II are related as apparatus for its practice and process. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another and materially different apparatus such as a balloon dissecting catheter or the apparatus as claimed can be used to practice another and materially different process such as treating total or partial occlusions in the body's vasculature.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Richard Gray on 2/26/07 a provisional election was made without traverse to prosecute the invention of Group I,

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claims 1-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DETAILED ACTION

Claims 27-34 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in telephone conversation with Attorney Richard Gray on 2/26/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Jungenheimer et al. (US-20020062130).

Jungenheimer discloses:

Regarding **claim 1**, an expandable structure (300), placeable in a stomach (para.0202), the expandable structure, when expanded is inherently capable of occupying a portion of the stomach; and an evacuator (4) that deflates the stomach around the expandable structure (para.0117) to form a gastric reduction pouch (i.e deform or compress tissue; para.0016, 0019, 0020).

Regarding **claim 2**, the expandable structure is placeable in the stomach immediately adjacent and distal to an esophageal orifice associated with the stomach (para.0202).

Regarding **claims 3-5, 16-18**, the expandable structure comprises an inflatable, compliant balloon (300, para.0107).

Regarding **claims 6 and 19**, the inflatable structure is a non-compliant balloon (the balloon is inherently non-compliant once the pressure has reached a maximum inside balloon).

Regarding **claims 7 and 20**, the evacuator extends distally from the expandable member and terminates within the stomach (fig. 6, para. 0202).

Regarding **claim 8**, a fastener (10) that maintains the gastric reduction pouch (para.0016, 0019).

Regarding **claims 9 and 21**, the fastener is capable of inwardly folding stomach tissue (para.0104; figs 1 and 2) and fastening serosa tissue to serosa tissue of the stomach.

Regarding **claims 10 and 22**, the fastener comprises a cylindrically shaped member having opposed ends and tissue engaging arms (fig.1, 19) radially extending from each of the opposed ends (figs 1-3).

Regarding **claims 11 and 24**, an endoscope (1) that extends through the expandable member (fig. 3).

Regarding **claims 12 and 25**, the expandable member forms a spherically shaped ring when expanded (fig. 6).

Regarding **claims 13 and 26**, the spherically shaped ring (fig. 6, 300) includes an axial passageway and wherein the evacuator (4) extends through the passageway (fig. 6).

Regarding **claim 14**, an expandable structure (300), placeable in a stomach (para.0202) and, when expanded, inherently occupying a fractional volume of the stomach; an evacuator (4) that deflates the stomach and draws the stomach to and around the expandable structure to form a gastric reduction pouch with stomach tissue (para.0117); and a fastener (10) that is operable to maintain the gastric reduction pouch (i.e deform or compress tissue; para.0016, 0019, 0020).

Regarding **claim 15**, the expandable structure (300) is capable of being placed in the stomach immediately adjacent and distal to an esophageal orifice associated with the stomach (para. 0202).

Regarding **claim 23**, the fastener (10) is carried by the evacuator (fig 3, 4).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PK
AU 3731
2/28/07



ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

3/2/07.